



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/664,000

09/16/2003

Kalim Mir

067024-5009

3911

9629 7590 03/25/2011
MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

03/25/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/664,000	Applicant(s) MIR, KALIM	
	Examiner FRANK LU	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,16,17,20,21,25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,16,17,20,21,25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on February 4, 2011 has been entered. The claims pending in this application are claims 4, 16, 17, 20, 21, 25, and 26. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of applicant's amendment filed on February 4, 2011.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on two applications, GB0106635.6, and GB0118879.6, filed in United Kingdom on March 16, 2001 and June 2, 2001 respectively. It is noted, however, that applicant has not filed certified copies of these application as required by 35 U.S.C. 119(b). Although applicant indicated that "[A]pplicant intends to submit these documents prior to grant of any patent based upon this application", since the office has not obtained these certified copies, this objection is maintained.

Claim Objections

3. Claim 4 is objected to because of the following informalities: (1) "which method comprises" in line 2 of the claim should be "which comprises" or "comprising"; (2) "individual immobilized molecules" in line 2 of step (i) should be "individual immobilized molecule"; (3) "in the array" in line 3 of step (i) should be "on the array"; and (4) "the identity of each molecule" in line 3 of step (i) should be "the identity of said each molecule".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4, 16, 17, 20, 21, 25, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 4 is rejected as vague and indefinite in view of step (i) because it is unclear where individual immobilized molecule is individually resolved and where the individual immobilized molecule is derived from. Please clarify.

7. Claim 4 is rejected as vague and indefinite in view of step (i). Since step (i) does not contain an immobilization step and “wherein” phrase is used to define the word or phrase that appears before the “wherein” phrase, the phrase “the identity of each molecule is known or determined prior to immobilization” does not make sense. Please clarify.

8. Claim 26 is rejected as vague and indefinite because it is unclear how, based on a label which can be detected by optical method, the electrode can transduce an electric signal so that the binding is detected by electric means when a target molecule binds to the labeled immobilized molecule. Please clarify.

Response to Arguments

In page 1, fifth paragraph of applicant’s remarks, applicant argues that “[A]pplicant notes that this claim provides for a second detection method for binding of a target molecule to the array. Specifically, binding can be detected by electrical means”.

Art Unit: 1634

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection because it is unclear how, based on a label which can be detected by optical method, the electrode can transduce an electric signal so that the binding is detected by electric means when a target molecule binds to the labeled immobilized molecule. In other word, it is unclear how an electric signal can be generated based on a label which can be detected by optical method.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 4, 16, 17, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramanian et al., (WO 00/06770, published on February 10, 2000).

Regarding claims 4, Balasubramanian et al., teach (i) providing a molecular array comprising a plurality of functional molecules (ie., polynucleotides with known sequences) immobilized to a solid phase (ie., the solid surface) at a density which allows individual immobilized molecules to be individually resolved, wherein each molecule in the array is spatially addressable (ie., by sequencing the array, see page 4, lines 19-27 and page 10, lines 14-21) and the identity of each molecule is known or determined prior to immobilization (ie., polynucleotides with known sequences) and (ii) labeling functional immobilized molecules on the array such that remaining labeled individual functional immobilized molecules (ie., the

Art Unit: 1634

fluorescent labeled polynucleotides) are spatially addressable and capable of being individually resolved by optical methods (ie., optical microscopy) as recited in claim 1 wherein the label can be read by optical methods (ie., optical microscopy) as recited in claim 16, and the label is a single fluorescent molecule (ie., a fluorescent label), nanoparticle or nanorod, or one of a plurality of fluorescent molecules, nanoparticles or nanorods as recited in claim 17 (see pages 2-4 and 10, claims 1-21 in pages 20 and 21 and Figure 2).

Regarding claims 20 and 21, Balasubramanian et al., teach that the molecules are selected from defined chemical entities, oligonucleotides, polynucleotides, peptides, polypeptides, conjugated polymers, small organic molecules or analogues, mimetics or conjugates thereof as recited in claim 20 (see page 6). Since Balasubramanian et al., teach that oligonucleotides on the array are chemically synthesized based on cDNA or genomic sequence (see page 14) and hybridize to an organism genomic DNA (see claim 32 in page 22), Balasubramanian et al., disclose that the molecules are cDNAs and/or genomic DNA as recited in claim 21.

Balasubramanian et al., do not disclose labeling only a portion of functional immobilized molecules on the array as recited in claim 4.

However, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 4 by labeling only a portion of functional immobilized molecules on the array in view of the prior art of Balasubramanian et al.. One having ordinary skill in the art would have been motivated to do so because, by labeling only a portion of functional immobilized molecules on the array, specific functional immobilized molecules on the array would be selected based on the labels of the specific functional immobilized molecules. One having ordinary skill in the art at the time the

Art Unit: 1634

invention was made would have a reasonable expectation of success to label only a portion of functional immobilized molecules (ie., labeling specific functional immobilized molecules) on the array based on the experimental requirements such that specific functional immobilized molecules on the array would be selected based on the labels of the specific functional immobilized molecules.

Response to Arguments

In page 1, sixth paragraph bridging to page 2, second paragraph of applicant's remarks, applicant argues: (1) "[A]pplicant submits that the array in Balasubramanian et al. relates to random arrays and where the array cannot be spatially addressable as required by the present invention. The phrase 'spatially addressable' is defined in the specification as 'signifies that the location of a molecule specifies its identity' (see specification at page 22, lines 22-25). On the contrary, the array in Balasubramanian contains molecules whose identity is NOT specified by their location in the array because their location is random. The molecules on the array are only spatially addressable after immobilisation. The amended claims provide for molecules on an array that are spatially addressable where the identity of each molecule is known or determined prior to immobilization. Balasubramanian discloses that single molecules may be arrayed by immobilisation to the surface of a solid support and that the array is produced by dispensing small volumes of a sample containing a mixture of molecules onto a suitably prepared solid surface, or by applying a dilute solution to the solid surface to generate a random array (see page 7). In other words, a mixture of molecules is dispensed randomly on the array and then identification of each molecule is carried out after immobilisation onto the array. The amended claims provide for a method of producing an array where a single species of molecules is

Art Unit: 1634

dispensed on the array in a defined location”; and (2) “the skilled person would not have been motivated to produce an array with spatially addressable molecules with any expectation of success because the cited reference discloses production of random arrays, which are entirely different than the arrays set forth in the amended claims”.

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. Since “determined prior to immobilization” in the phrase “wherein each molecule in the array is spatially addressable and the identity of each molecule is known or determined prior to immobilization” in step (i) of claim 4 is an optional phrase and the phrase “wherein each molecule in the array is spatially addressable and the identity of each molecule is known or determined prior to immobilization” can be read as “wherein each molecule in the array is spatially addressable and the identity of each molecule is known after the immobilization or prior to the immobilization”. Since Balasubramanian et al., teach that “[A]n array of the invention may also be used to generate a spatial addressable array of single polynucleotide molecules. This is the simple consequence of sequencing the array” (see page 4, lines 19-21), “term ‘spatially addressable’ is used herein to describe how different molecules may be identified on the basis of their position on an array” (see page 10, lines 16 and 18) and “the arrayed polynucleotide is of known sequence” (see page 21, claim 16), Balasubramanian et al., disclose that each molecule in the array is spatially addressable (ie., by sequencing the array) and the identity of each molecule is known (ie., polynucleotides with known sequences) as recited in claim 4.

Art Unit: 1634

11. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramanian et al., as applied to claims 4, 16, 17, 20, and 21 above, and further in view of Edman et al., (US Patent No. 6,706,473B1, filed on January 24, 2000).

The teachings of Balasubramanian et al., have been summarized previously, supra.

Balasubramanian et al., do not disclose that each of the labeled immobilized molecules in step (ii) are immobilized onto a single electrode as recited in claim 25.

Edman et al., teach immobilization of fluorescence labeled DNA oligonucleotides on a streptavidin-agarose and Mn_2O_3 coated amorphous silicon electrode (see column 11, second paragraph and Figures 50A and 50B).

Art Unit: 1634

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 25 wherein each of the labeled immobilized molecules in step (ii) are immobilized onto a single electrode in view of the prior arts of Balasubramanian et al., and Edman et al.. One having ordinary skill in the art would have been motivated to do so because Edman et al., have shown immobilization of fluorescence labeled DNA oligonucleotides on a streptavidin-agarose and Mn_2O_3 coated amorphous silicon electrode (see column 11, second paragraph and Figures 50A and 50B) and the simple substitution of one kind of immobilization method (ie., the immobilization method taught by Balasubramanian et al.,) from another kind of immobilization method (ie., the immobilizing polynucleotides on a single electrode taught by Edman et al.,) during the process of producing the molecular array recited in claim 4, in the absence of convincing evidence to the contrary, would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since the immobilization method taught by Balasubramanian et al., and the immobilization method taught by Edman et al., are used for the same purpose (ie., immobilizing a plurality of functional molecules such as polynucleotides).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements in such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. In re Rose 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Art Unit: 1634

Response to Arguments

In page 2, third paragraph of applicant's remarks, applicant argues "[T]he deficiencies of Balasubramanian are discussed above. Edman alone, does not disclose or suggest all of the features of claim 25. Withdrawal of the rejection is requested".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection because Balasubramanian et al., do teach claim 4 (see above

Response to Arguments related to the rejection item No. 8) and the rejection is based on a combination of Balasubramanian et al., and Edman et al..

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. No claim is allowed.

Art Unit: 1634

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen, can be reached on (571)272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frank W Lu /
Primary Examiner, Art Unit 1634
March 23, 2011

Application/Control Number: 10/664,000

Page 12

Art Unit: 1634